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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,433	11/21/2005	Sang-Kyu Lee	NAMNP0103US	5833

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EXAMINER	
JOIKE, MICHELE K	
ART UNIT	PAPER NUMBER
1636	

MAIL DATE	DELIVERY MODE
12/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,433	LEE ET AL.	
	Examiner	Art Unit	
	MICHELE K. JOIKE	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/10/08*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,7-11 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,7-11 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed October 10, 2008. Claims 1-3, 5, 7-11 and 14 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed June 10, 2008 that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 is dependent upon a cancelled claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 10 and 11 stand rejected under 35 U.S.C. 102(b) as being anticipated by Ye et al.

Response to Arguments Concerning Claim Rejections – 35 USC § 102 (b)

Applicant's arguments filed October 10, 2008 have been fully considered but they are not persuasive.

The following grounds of traversal are presented:

Applicants argue that the luciferase reporter gene disclosed in Ye et al is different in that a biological regulatorv molecule" of the present invention comprises T cell specific Lck, CD2 promoter and pancrease-specific insulin promoter, which actually carry out a regulatory function, whereas the luciferase is only a reporter.

Applicant's arguments have not been found persuasive for the following reasons.

Applicants do not claim use of a T cell specific Lck, CD2 promoter or pancrease-specific insulin promoter. Ye et al teach use of a Gal4 promoter, which satisfies the claim language of "wherein the biological regulator is a promoter…."

However, Applicant's amendments have caused the new 35 USC 103(a) rejection for claims 7-9 and 14, stated below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7-9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ye et al as applied to claims 1-3, 5, 10 and 11 above, and further in view of Zuckerman.

Ye et al (Phar. Res. 19(9): 1302-1309, 2002, specifically pp. 1302-1305, especially Fig. 1) teach a binding complex comprising a chimeric protein (protein fusion) comprising an HA epitope, a Gal4(DBD)-VP16 and a His tag. The chimeric protein can also include a Tat or VP22. Ye et al teach a vector (peptide transducing recombinant (PTD) expression vector) encoding the above complex, including a promoter, that is co-transformed with a reporter plasmid encoding a luciferase gene linked to five tandem

repeats of the Gal4 binding site (inducible promoter) (p. 1304-05). The chimeric protein is produced, and the reporter plasmid binds to the chimeric protein completing the binding complex. The binding complex is moved from the culture medium to the nucleus as evidenced by activation of the reporter gene (p. 1304). See specifically Fig. 1. The vector encoding the chimeric protein can also contain a sequence encoding a nuclear localization sequence (p. 1303). The Gal4 promoter is a promoter that expresses a gene in different cell types, however, it inherently will express at different levels depending on the cell or species, etc..

Ye et al also teach a method for delivering the two vectors into HEK293 cells (Materials & Methods). The PTD vector is made as described above, and expression of the vector produces the chimeric protein in HEK293 cells. The binding complex is formed when the reporter plasmid (also made as described above) binds the chimeric protein. Co-culture assays are performed through adding cells to culture plates. Again, an NLS sequence can be added to the PTD vector. However, they do not teach delivery of the binding complex through routes including intramuscularly.

Zuckerman (Br J Gen Pract. 50(458): 753, 2000) teach delivering DNA vaccines intramuscularly. (Rabinovitch et al (Allergy, Volume 54, Issue 7, Pages 662-668, 1999) teach that proteins are also able to be delivered intramuscularly. Therefore, it would follow that a binding complex of DNA and protein could be delivered intramuscularly.)

The ordinary skilled artisan, desiring to use an intramuscular delivery, would have been motivated to combine the teachings of Ye et al teaching a binding complex for delivering DNA/RNA into the cytoplasm or nucleus, comprising a fusion protein of

PTD (Sim-2, Tat, ANTP, MTS) with one or more binding proteins having a DNA binding domain; a DNA binding sequence which is specifically bound to the DNA binding domain; and an inducible promoter expressing a gene specifically in specific species, tissues, organs or cells, with the teachings of Zuckerman teaching delivering DNA intramuscularly because Zuckerman et al state that intramuscular delivery is recommended to provide optimal immunogenecity. It would have been obvious to one of ordinary skill in the art to use intramuscular delivery because Zuckerman teaches that intramuscular injection minimizes adverse reactions. Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered, absent evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Allowable Subject Matter

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE K. JOIKE whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/
Primary Examiner, Art Unit 1636

Michele K Joike
Examiner
Art Unit 1636